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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,151	10/27/2003	Stephen C. Porter	03-116 (US01)	6462

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,151	PORTER, STEPHEN C.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,20-30,32-38 and 40-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,20-30,32-38 and 40-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/2007
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5, 10, 12, 15, 16, 20, 30, 32, 33 and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/694927 in view of Martinez (US 2004/0098028) . The claims of the copending application claim all the elements of the instant application including an occlusive member that is a coil having an axial lumen, an active element that comprises an agent carrier that contracts. The claims of the copending application do not disclose that the active carrier is a hydrogel or that the active element is contained entirely within the lumen. Martinez discloses a similar occlusive element having a coil with axial lumen, and an active element that includes a

hydrogel where the active element is entirely within the lumen of the coil. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the known technique of incorporating the active agent entirely within the lumen to the known device of the copending claims and the combination would have yielded predictable results.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 4-6, 7, 10, 11, 14-16, 20, 21, 30 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Martinez (US 2004/0098028).

5. Martinez discloses vaso-occlusive device comprising an elongate occlusive member that is a helically wound coil defining a longitudinal axis (13) having an elongate axial lumen and an active element (12 and 11) having a pre-deployment configuration carried entirely within the lumen (fig. 2). No portion of the pre-deployed

active element is located outside of the lumen. The active element is configured to radially expand to a deployed configuration without application of mechanical force when placed in the body to cause the occlusive member to retain its shape (Figs. 3 and 4). Within time, as the properties of the blood around the device change (i.e. temperature, pH, or salt content) it is inherent that the hydrogel will lose some of its moisture to the environment and will contract (even if only at a microscopic level). The hydrogel will still be expanded enough to hold cause the coil to retain its shape but will have contracted radially, thus meeting the limitations of the claim. Note that the claimed invention does not require the actual act of the active element contracting to cause the coil to retain its shape since during the act of the active element contracting, the coil will also be moving and reshaping, thus not retaining its shape. Rather, the claimed invention only requires that the final product of a contracted active element/hydrogel causes the coil to retain its shape since it is after the act of contracting and reshaping the coil that the active element causes the coil to retain its shape. The active element is secured to the occlusive member at one or both ends and at one or more locations along the length of the occlusive member (by I 13 along the length and 14, 15 at the ends; see Figs. 2 and 4). The active element is a hydrogel comprising polysaccharide with a cross linking polymer (Para [0024]). The active member has an elongate shape when it is undeployed (Fig. 2) and a coil shape when it is deployed (11 and 12, Fig. 3). The active element when in the body may be expanded to have a cross sectional dimension that is at least 100% of the internal diameter of the occlusive member and

may be expanded to between 110% and 200% of the internal diameter of the occlusive member (Para [0037]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-8, 14, 15, 20, 21, 27-30, 32-35, 38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 2004/0098023) in view of Rosenthal (US 7,066,904).

8. Lee discloses a vaso-occlusive device having an elongate occlusive member having an axial lumen (14, For example, Figs. 3, 6,7) and an active element carried within the lumen which causes the occlusive member to retain its shape (Para [0016]). Lee discloses several ways that the fibrous structure can be attached to the core (Para [0044]) including adhesive. The active element has an elongate shape (Figs 3-8) and the occlusive member is a coil (Figs. 6, 9-17). The active element is a polymer (Para 0033)

9. **Regarding claims 1, 4, 30, 32 and 40,** Lee does not disclose that the active element is retained entirely within the lumen with no portion of the pre-deployed active element located outside the lumen. Lee does not explicitly state where along the core the fibers are attached.

10. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to determine that the attachments would be at the distal and proximal ends in order to avoid having extraneous material extending beyond the therapeutic parts of the device (i.e. the fibers). In other words, it would be common sense to use as little core material as possible and as much fiber as possible when constructing the device. It would be well within the skill of the ordinary artisan to achieve these results with the methods of attachment disclosed by Lee.

11. **Regarding claims 1, 30, 32 and 40**, Lee does not disclose that the active element contracts to a deployed configuration but rather discloses that the active element will expand. Lee discloses that the active element can be a wire basket or an expandable balloon (Para [0052]). Lee also contemplates the idea incorporating a bioactive agent into the core element but does not disclose details as to how this would be done.

12. Rosenthal discloses the use of balloon catheter coated with hydrogel for delivering drugs. Rosenthal disclose that the hydrogel can expand or contract in order to release the drug (bioactive agent) (Col 6, line 55-64). The active element is a polymer hydrogel that is swollen with an aqueous ionic solution that will diffuse out of the gel upon contact with blood (Col 2, lines 32-57). The polymer can be polymethacrylate (Col 3, line 37). The polymer is thermoresponsive (Col 3, line 60).

13. Lee provides the base device of a core element that can incorporate drug delivery and a core element that can be an expandable balloon. Rosenthal provides a known method (via hydrogel) for delivering a drug with a balloon catheter. It would have

been obvious to one having ordinary skill in the art at the time of the invention to enhance the device of Lee with the method of drug delivery via hydrogel, since the method was made part of the ordinary capabilities of one skilled in the art based upon the teachings of Rosenthal.

14. The modified Lee device meets the limitations of the independent claims as such. When the entire device is delivered, the core element (12) (being a balloon or basket coated with a drug delivering hydrogel) is expanded and causes the coil (14) to retain its shape when first deployed. The hydrogel will contract (thus the active element contracts to a second deployed configuration) upon interaction with its environment (without the application of mechanical force) to deliver the drug. At the same time the balloon continues to cause the occlusive member to retain its shape.

15. **Regarding claims 28 and 29** Lee in view of Rosenthal does not disclose the time frame for the drug delivery or contraction of the active element, however it would have been well within the skill of the ordinary artisan at the time of the invention to determine the composition necessary to deliver the drug, thus contracting the hydrogel within the claimed time depending on the intended use of the drug.

16. **Claims 9-13, 22-26, 28, 29, 36 and 37are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (US 2004/0098023) in view of Rosenthal (7,066,904) as applied above and further in view of Sawhney (US Pub 2001/0046518).**

17. Lee in view of Rosenthal discloses the invention substantially as claimed as stated above except for the material that makes up the hydrogel.

18. Sawhney discloses a hydrogel used for delivery of therapeutic agents. The hydrogel comprises polypropylene glycol or poly-hydroxyalkyl methacrylate (Para 37, 38). The hydrogel comprises polysaccharides, hyaluronic acid or heparin (Para 35). The hydrogel further comprises chemical cross-linking agents (Para 31). The hydrogel is thermoresponsive (Para 40). The hydrogel comprises a polyelectrolyte (Para 38) and undergoes an ionic concentration induced shape change (Para 40). The active element can be a fiber (Para 37 and 62), which undergoes a thermally induced phase change or a pH induced phase change (Para 40). The active element is activated within about 10-20 minutes of being placed in a body (Para 28).

19. Lee in view of Rosenthal provides the base of an occlusive coil with a core member that uses hydrogel to deliver bioactive agent. Sawhney provides the teaching of materials and characteristics of hydrogels. It would have been obvious to one having ordinary skill in the art at the time of the invention to enhance the modified device of Lee with the different materials and characteristics of hydrogels, since the teachings were made part of the ordinary capabilities of one skilled in the art based upon the teachings of Sawhney.

Response to Arguments

20. Applicant's arguments with respect to claims 1-16, 20-30, 32-38 and 40-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

21. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 09/26/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Todd E. Manahan
SPE 3731

eh

12/6/07